Stratton VA
Research & Development Office
Standard Operating Procedure

REQUIREMENTS FOR CONDUCTING VA-APPROVED INTERNATIONAL RESEARCH INVOLVING HUMAN SUBJECTS, HUMAN BIOLOGICAL SPECIMENS, OR HUMAN DATA

PURPOSE: The Veterans Health Administration (VHA) Directive 2005-050 provides policy that requires permission be granted by the Chief Research and Development Officer (CRADO), or designee, prior to initiating or conducting Department of Veterans Affairs (VA)-approved international research involving human subjects, human biological specimens, or human data. NOTE: This policy is in addition to other applicable regulations and policies including Title 38 Code of Federal Regulations (CFR) 16.101(h).

BACKGROUND NOTE: All research must be approved by the Stratton VAMC Research and Development (R&D) Committee.

For the purposes of this standard operating procedure, international research is defined as any VA-approved human subjects research conducted at international sites (not within the United States (U.S.), its territories, or Commonwealths) or any VA-approved research using either human biological specimens or human data originating from international sites. Multi-site trials are only covered under this definition if:

(1) VA is the sponsor,

(2) VA functions as the coordinating center,

(3) VA subcontracts to a foreign site, or

(4) The principal investigator (PI) for the total project is a VA investigator.

NOTE: This Directive does not apply if VA is only one of the participating sites and the trial does not meet the preceding conditions.

Investigators and review committees are faced with diverse considerations when planning or reviewing human research at international sites. These vary depending on the specific research and the site of the research. Of utmost importance is that all individuals who participate as subjects in research at international sites are provided appropriate protections that are in accord with those given to research subjects within the U.S. There are a number of general principles upon which these protections are based including respect for persons, beneficence, and the sharing of benefits and burdens from the research. Also important are understanding and respect for the

community, the group, the culture, and the environment of persons from whom the data are derived. NOTE: To address these issues, this Directive and associated guidance have been developed; which can be found on ORD's Web site at: www.va.gov/resdev

REFERENCES: VHA DIRECTIVE 2005-050, November 2005
Title 38 Code of Federal Regulations (CFR) 16.101(h)

POLICY: It is VHA policy that permission must be obtained from the CRADO or designee prior to initiating any VA-approved human subjects research **conducted at international sites** (not within the U.S., its territories, or Commonwealths) or to VA-approved research using either human biological specimens or human data originating from an international sites. NOTE: This policy applies regardless of the funding source (funded or unfunded) and to research conducted through any mechanism of support including agreements, Memoranda of Understanding (MOU), Cooperative Research and Development Agreements (CRADA), grants, or contracts.

ACTION

- **Office of Research and Development (ORD).** ORD is responsible for the review of, and action on, all requests for permission to conduct VA-approved research involving human subjects, or human biological specimens, or human data from international sites. NOTE: The CRADO, or designee, will not grant permission for an international research project involving prisoners as research subjects.
- **Office of Research Oversight(ORO).** ORO is responsible for the oversight of all on-going human subjects research conducted or supported by VA including research conducted at international sites.
- **Facility Director.** The facility Director is responsible for:

  Approving the request for permission to conduct international research prior to forwarding it to the CRADO for action.

  Ensuring permission has been obtained from the CRADO, or designee, for the international research prior to its initiation by an investigator at the facility.

  NOTE: Information on how to request permission may be referenced on the following Web site at: www.va.gov/resdev

- **Principal Investigator (PI).** The PI is responsible for:

  Conducting research in compliance with all applicable VHA and other Federal regulations and policies including those for protecting human subjects, tissue

banking, use of databases, Federal criminal laws, and the Standards of Ethical Conduct for Employees of the Executive Branch.

Obtaining permission from the CRADO, or designee, that allows the initiation of international research subject to VHA policy.

Informing the Stratton VAMC Institutional Review Board (IRB), the Stratton VAMC R&D Committee, the Associate Chief of Staff for R&D, ORO, and other individuals or entities (as required by the facility's policies and VHA Handbook 1058.1) of all unexpected or adverse events involving human subjects or any aspect of the conduct of the study.